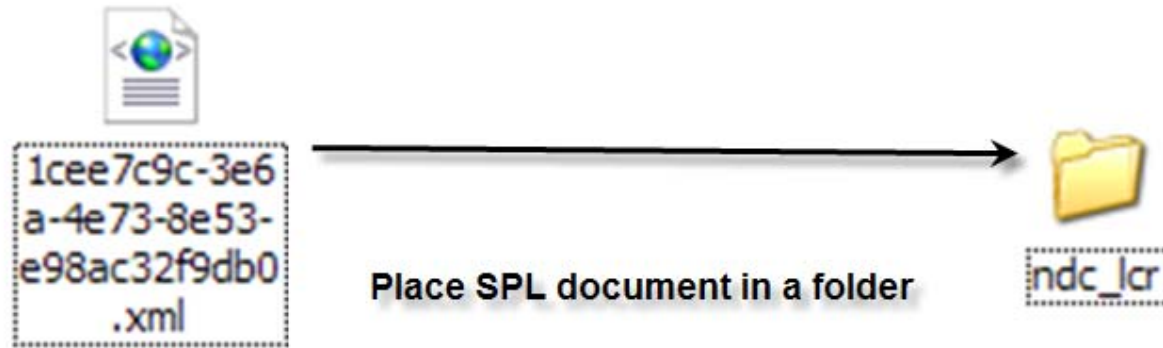


Submitting SPL R4 Files Via FDA “OC” Gateway

Basic Instructions Sending SPL
Documents to Register a Drug
Establishment or List a Drug

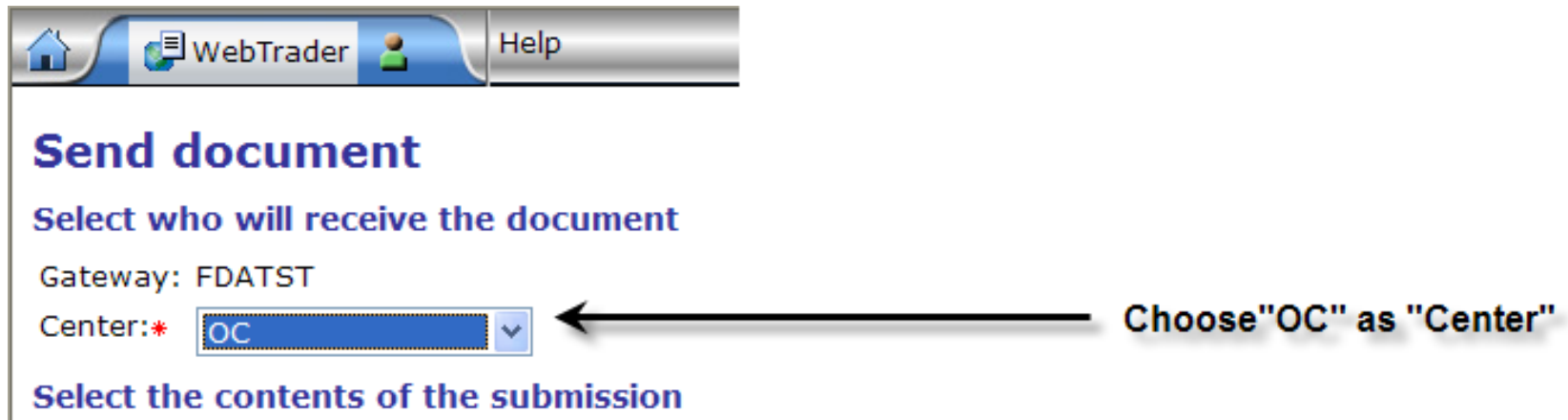
Version 1.0

Place SPL File in Folder



- Place SPL document in a folder.
- Ensure that SPL file name is document root ID with “.xml” as file name extension.
- Only **ONE** SPL document per folder. If applicable, image files (jpeg) may accompany listing SPL document in folder.

Choosing “Center”



WebTrader Help

Send document

Select who will receive the document

Gateway: FDATST

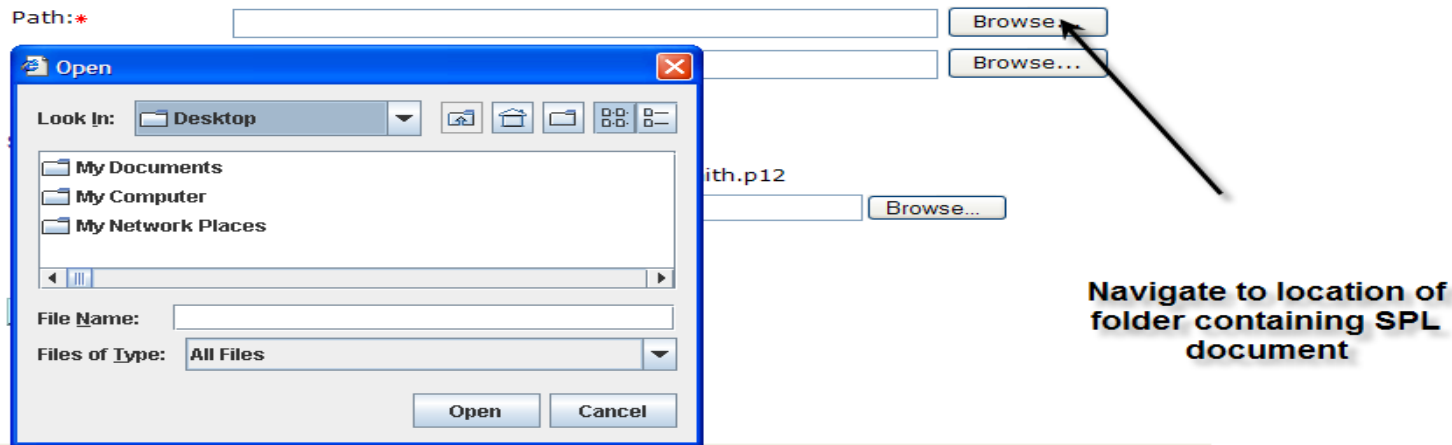
Center: * ▼

Select the contents of the submission

Choose "OC" as "Center"

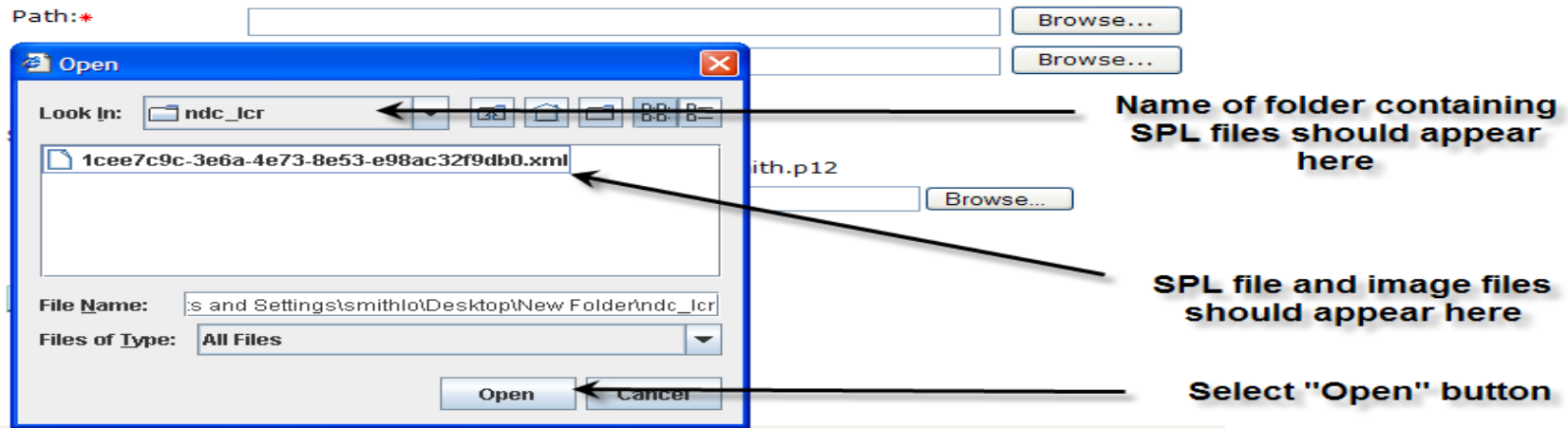
- Select “OC” as the FDA Gateway “center.”
- NDC Labeler Code, Establishment Registration, & Content of Labeling/Listing SPL documents submitted for the purpose of registering a drug establishment and listing a drug product should be sent via “OC.”

Navigate to Folder w/SPL



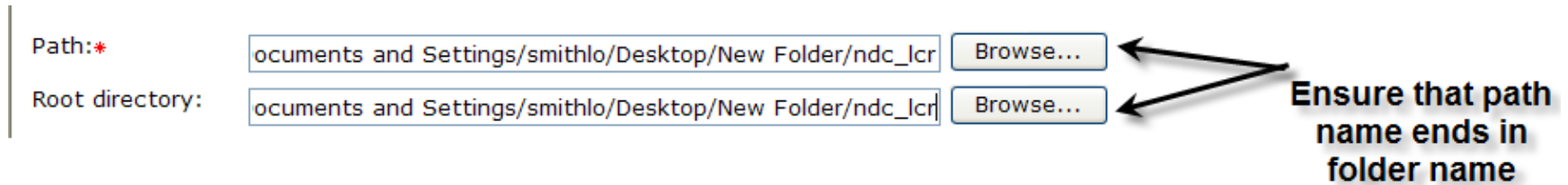
- Click browse button to navigate to location of folder containing SPL file (and, if applicable, associated image files.)

Selecting SPL Submission



- Ensure that you are sending folder.
- Check to be sure that you are not sending a folder within a folder
- Select "Open" to continue.

Checking Path Name



- Ensure that path name ends in the name of folder which contains the SPL document and JPEG files.
- If path ends in file name, then you are only sending the file and not the folder containing files.

Selecting Submission Type

Submission type: *  **Select submission type "SPL"**

- Use drop-down menu to select submission type “SPL.”
- If submission type “SPL” does not appear, you have chosen the wrong center and not “OC.”

Verify or Select Digital Certificate



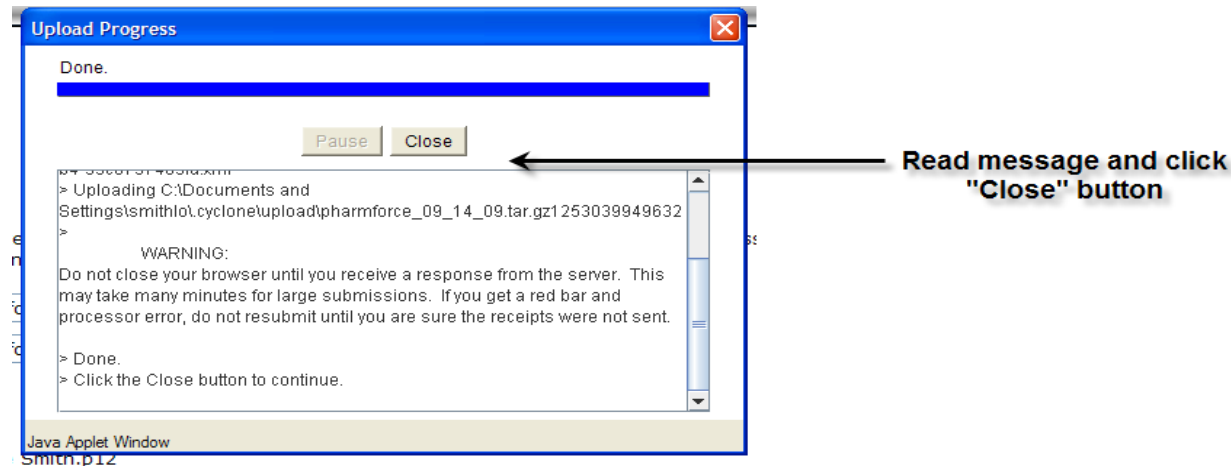
- Verify that your digital certificate is being used.
- Or browse to the location of the digital certificate on your computer.

Sending the Submission



- Select the “Send” button.
- Enter your password to unlock signing certificate.
- Select the “OK” button

Completing Gateway Submission



- Read message in prompt window
- Select "Close" button